Review of Trigger Point Therapy for the Treatment of Myofascial Pain Syndromes

Kimberly Ting1, Albert Huh1, Carlos J. Roldan1,2*

1Department of Pain Medicine, The University of Texas MD Anderson Cancer Center, Houston, Texas, USA
2McGovern Medical School at The University of Texas Health Science Center at Houston (UTHealth), Houston, Texas, USA

Abstract

Scope of the investigation: No standard protocol has been established for the treatment of myofascial pain syndrome (MPS). Invasive therapies such as dry needling and trigger point injection (TPI) with active pharmacological agents are commonly used. Growing evidence suggests the efficacy of TPI is independent of the injectate selected. Normal saline (NS) solution has been described as an efficient injectate used in TPI for the treatment of MPS.

Methods: A broad literature search was performed to compare the use of NS and other pharmacological agents as the injectate in TPI for the treatment of MPS.

Results: We identified 13 reports comparing the safety and efficacy of NS with that of botulinum toxin A or local anesthetic with or without steroid in TPI.

Conclusion: Pain of myofascial origin can be adequately treated with TPI independent of the injectate used. The use of NS in TPI offers lower cost, safety, and a more favorable side effect profile than other TPI injectates.

Introduction

Myofascial pain syndrome (MPS) is characterized by painful manifestations originating in the muscles and fascia. The etiology of MPS includes trauma, repetitive muscle strain, physical inactivity, skeletal asymmetry, poor posture, systemic disease, and neuromusculoskeletal lesions1,2. MPS is also thought to be caused by trigger points, taut bands of skeletal muscle that can produce local and referred pain when provoked3,4,5. Overall, MPS has a lifetime prevalence of up to 85% in the general population and more often affects women between 15 and 40 years of age6,7. In a study by Skootsky et al., the authors found that among the patients who presented to a primary care office visit for pain, 30% had pain that originated in the myofascial tissue4. The diagnosis of myofascial pain is even more prevalent in patients presenting to a pain management clinic, with proportions cited as high as 93%4.

While myofascial pain can be present as the sole pain generator, it is not uncommon for it to be part of a constellation of other pain syndromes. Although the connections are not clearly understood, MPS has been associated with other pain conditions such as migraines, fibromyalgia, spinal pain, and osteoarthritis5,8,9. In patients with MPS, treatment should not be focused on the symptomatic relief of the myofascial pain alone; a comprehensive approach should include managing the underlying conditions and preventing recrudescence of the myofascial pain.

Treatment options for MPS range from conservative approaches to invasive procedures. Some studies have shown nonsteroidal
anti-inflammatory drugs to be an effective treatment in myofascial pain; however, these are often used in conjunction with other treatments. Other pharmacological agents such as antidepressants, anti-convulsants, and narcotics are also used to treat myofascial pain, but studies have shown limits in their effectiveness. A non-randomized study by Haviv et al. with 42 patients showed that amitriptyline/nortriptyline and gabapentin have been used successfully in the treatment of myofascial pain; however, these results have not been validated. Other studies have reported that home stretching exercises and physical therapy are both effective in reducing pain and can be used as adjuncts in any treatment program.

Invasive procedures aimed at diffusing the trigger point of the muscle that is compromised are extensively used in different clinical settings and have shown efficacy in the treatment of MPS. These include dry needling and trigger point injection (TPI). Based on the theories behind the pathophysiology of MPS, mechanical disruption of the trigger point has emerged as a practical treatment option. In a review by Cummings et al., the authors concluded that direct needling of myofascial trigger points was an effective treatment. This finding has been supported by other studies.

TPIs with various injectates are commonly used to treat MPS. However, numerous authors have called into question the traditional use of local anesthetics mixed with steroids in TPIs. Thus, botulinum toxin A (BoNT-A) has emerged as an alternative injectate; however, in a comprehensive literature review, Zhou et al. found mixed results when using this agent as the injectate in TPIs.

Previous and recent studies using normal saline for TPI have shown great results in treating MPS. In a study by Roldan et al., the authors found that normal saline was non-inferior when compared to traditional treatment mixes of local anesthetics plus triamcinolone acetonide. This calls into question the use of injectates other than normal saline, given that normal saline is very inexpensive and has no side effects. This review article analyzes the current literature on the effectiveness of normal saline compared to these other injectates on outcomes including pain, stiffness, and quality of life.

Data Acquisition

A comprehensive search of the literature was performed in September 2020 using the Medline (Ovid), Embase (Ovid), and Scopus databases. The search applied both controlled vocabulary and natural language terms for saline, normal saline, trigger point injections, and trigger point therapies. Results were limited to English language and human studies published from 2008 to the present. A total of 24 citations and abstracts were identified by this search. Of those 24 citations and abstracts, six were irrelevant to the topic, one was for a review article, one was for an article that was retracted, and one was for an article that we could not access/obtain, resulting in a total of 15 articles. Of these articles, most compared local anesthetic to normal saline, five compared BoNT-A to normal saline, and two compared normal saline to local anesthetic plus steroid, the conventional active drug mixture (CADM) (Table 1).

Table 1: Overview of the randomized controlled trials in trigger point therapy using injectate included into the review

<table>
<thead>
<tr>
<th>Reference</th>
<th>Type of Study</th>
<th>Anatomical Location</th>
<th>Size</th>
<th>Intervention</th>
<th>Primary Outcomes</th>
<th>Secondary Outcomes</th>
<th>Adverse events/Side effects</th>
<th>Limitations</th>
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<tbody>
<tr>
<td>Ojala, T. A., et al. (2010)</td>
<td>Double-blind, randomized, and controlled crossover trial</td>
<td>Neck-shoulder</td>
<td>N=31</td>
<td>Group 1: Saline containing 5 units of botulinum toxin A</td>
<td>The soft tissue stiffness of single neck muscles is not changed after injections of saline or small doses of botulinum toxin A</td>
<td>No clear correlation between soft tissue stiffness and self-reported or clinically assessed pain and disability</td>
<td>No statistically significant side effects in any groups</td>
<td>Small sample size</td>
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<td>Roldan, C. J., et al. (2019)</td>
<td>Randomized, blinded, controlled, non-inferiority trial</td>
<td>Iliocostalis lumbrorum, iliopectoralis thoracis, quadratus lumbrorum, paraspinal, paraspinal - thoracic, paraspinal - lumbar, periformis, gluteus medius, trapezius, latissimus dorsi</td>
<td>N=48</td>
<td>Group 1: N=23; TPI with normal saline (NS)</td>
<td>Immediately after TPI, the mean pain intensity was reduced by 5.48 in the NS group (p ≤ 0.001) and 5.68 in the CADM group (p ≤ 0.001). Overall, the mean pain scores from prior to the TPI to ED discharge were reduced by 6.17 (p ≤ 0.001) in the NS arm and 5.96 (p ≤ 0.001) in the CADM arm. The size of the effect for the NS arm was 2.88, and 1.04 patients would need to receive treatment to observe a benefit. The size of effect for the CADM arm was 2.51, and 1.08 patients would need to receive treatment to observe a benefit.</td>
<td>No statistically significant side effects in any groups</td>
<td>Small sample size. Patients received a heterogenous quantity and types of pain medications prior to the trigger point injections.</td>
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<tr>
<td>Reference</td>
<td>Design of Study</td>
<td>Target Muscles</td>
<td>N</td>
<td>Groups</td>
<td>Outcome</td>
<td>Side Effects</td>
<td>Notes</td>
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<td>Sabatke, S., et al. (2015)</td>
<td>Randomized, controlled, double-blind study</td>
<td>Temporalis muscle for masticatory myofascial pain syndrome, fibromyalgia, and headache</td>
<td>47</td>
<td>Group 1: N=16 control</td>
<td>Pain was reduced in 87.71% of patients injected with saline and 100% injected with anesthetic. Similar results were obtained for headache frequency. With regard to headache intensity, the injection groups differed from the control group, but not between themselves.</td>
<td>None</td>
<td>Small sample size. Only female participants.</td>
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<td>Bakunas, C., et al (2015)</td>
<td>Randomized, double-blind trial</td>
<td>Trapezius, gluteus medius/minimus, iliocostalis thoracis/lumborum, quadratus lumborum, paraspinal muscles</td>
<td>44</td>
<td>Group 1: TPI with normal saline (NS)</td>
<td>Similar duration of pain relief at 2-week follow-up</td>
<td>No statistically significant side effects in any groups</td>
<td>Small sample size</td>
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<td>Benecke, R., et al (2011)</td>
<td>Randomized, double-blind, placebo-controlled trial</td>
<td>Cervical, shoulder muscles</td>
<td>153</td>
<td>Group 1: N=81 TPI with botulinum toxin A (BoNT-A)</td>
<td>BoNT-A group experienced statistically significant more days per week without pain at week 4 and statistically significant more days per week with no or mild pain at week 8. Duration of daily pain reduced in BoNT-A group compared with NS at weeks 9 and 10. BoNT-A group had statistically significant reduced mean number of trigger points. Pain intensity for all trigger points was statistically significantly lower in the BoNT-A group compared to NS from week 4 to week 12. Physicians’ global assessment, patients’ global assessment statistically favored BoNT-A over placebo at weeks 8 and 12.</td>
<td>No statistically significant side effects in any groups</td>
<td>Optimal dose and time course of treatment effects not yet established; thus may not have been appropriate for all patients.</td>
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<td>Boelens, OB, et al (2013)</td>
<td>Randomized, double-blind, placebo-controlled trial</td>
<td>Abdominal wall</td>
<td>48</td>
<td>Group 1: N=24 TPI with lidocaine 1%</td>
<td>Lidocaine group showed statistically significantly higher proportion of patients achieving at least 50% improvement in pain perception on VAS and/or an improvement of at least 2 points on VRS during physical examination 15-20 min after TPI compared with before</td>
<td>No statistically significant side effects in any groups</td>
<td>Cannot account for different location of anterior cutaneous nerve entrapment in patients, lidocaine may not have reached exact point of entrapment as freehand injection technique used, short follow-up duration (15-20 min)</td>
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<tr>
<td>Study</td>
<td>Design</td>
<td>Comparator</td>
<td>Participants</td>
<td>Interventions</td>
<td>Outcomes</td>
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<td>Carroll, A. et al. (2008)</td>
<td>Randomized, double-blind, placebo-controlled study</td>
<td>Trapezius, splenius capitis</td>
<td>N=37</td>
<td>Group 1: N=20 TPI with botulinum toxin A (BoNT-A) Group 2: N=17 TPI with normal saline (NS)</td>
<td>No statistically significant difference in tenderness to palpation, visual analogue pain scale, VAS-M, VAS-DI, and cervical range of motion</td>
<td>None</td>
<td>Small sample size, possible insufficient control</td>
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<tr>
<td>Dessie, SG et al. (2019)</td>
<td>Double-blind, randomized, placebo-controlled trial</td>
<td>Pelvic floor muscles</td>
<td>N=59</td>
<td>Group 1: N=30 TPI botulinum toxin A (BoNT-A) Group 2: N=29 TPI with normal saline (NS)</td>
<td>No difference in participant-reported pain on palpation of the most painful pelvic floor muscle at 2 weeks</td>
<td>No significant difference in pain on palpation at 4 and 12 weeks. No significant difference reported pain on visual analogue scale.</td>
<td>No statistically significant side effects in any groups</td>
<td>Placebo effect, small sample size, limited generalizability, multiple clinicians administering the injections, follow-up limited to 12 weeks, presence of multiple pain disorders</td>
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<tr>
<td>Giladi, H. et al. (2014)</td>
<td>Double-blind, randomized, placebo-controlled trial</td>
<td>Lower back muscles</td>
<td>N=43</td>
<td>Group 1: N=22 TPI with bupivacaine Group 2: N=21 TPI with normal saline</td>
<td>Patients receiving bupivacaine did not report a benefit at the end of the study compared to patients receiving normal saline</td>
<td>Decreased number of trigger points and increase in median pressure algometry measurements in both groups</td>
<td>No statistically significant side effects in any groups</td>
<td>Small sample size</td>
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<tr>
<td>Harden, RN et al. (2009)</td>
<td>Double-blind, randomized, placebo-controlled clinical trial</td>
<td>Trapezius, sternocleidomastoid muscle, splenius capitis</td>
<td>N=23</td>
<td>Group 1: N=12 TPI with botulinum toxin A (BoNT-A) Group 2: N=11 TPI with normal saline (NS)</td>
<td>BoNT-A group reported greater reductions in headache frequency during the first part of the study, but these effects dissipated by week 12. Reductions in headache intensity over time did not differ significantly between groups</td>
<td>No significant difference in range of motion planes, trigger point threshold, and psychological measures</td>
<td>No statistically significant side effects in any groups</td>
<td>Small sample size</td>
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<td>Karadas, O. et al. (2013)</td>
<td>Double-blind, randomized, placebo-controlled clinical trial</td>
<td>Frontal, temporal, maseter, SCM, semispinalis capitis, trapezius, splenius capitis</td>
<td>N=108</td>
<td>Group 1: N=27, TPI with normal saline (NS) Group 2: N=27, TPI with 0.5% lidocaine</td>
<td>The group that received 5 lidocaine injections had significantly reduced frequency and severity of pain at 2, 4, and 6 months based on visual analogue scores and frequency of painful days per month</td>
<td>No statistically significant side effects in any groups</td>
<td>Small sample size, short duration of follow-up</td>
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<tr>
<td>Karadas, O. et al. (2013)</td>
<td>Double-blind, randomized, placebo-controlled clinical trial</td>
<td>Muscles innervated by C1-C3 and trigeminal nerve, exit points of CN V, and around superior cervical ganglion</td>
<td>N=48</td>
<td>Group 1: N=24 TPI with lidocaine 0.5% Group 2: N=24 TPI with normal saline (NS)</td>
<td>Lidocaine group had statistically significant decrease in number of painful days in a month, visual analogue scale, amount of analgesic use in month, Hamilton depression score, and Hamilton anxiety score</td>
<td>None</td>
<td>No statistically significant side effects in any groups</td>
<td>Small sample size</td>
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Pathophysiology of Trigger Points

Several theories exist about the proposed pathophysiology of trigger points. One involves the sensitization of nerve fibers, whereby persistent sensory input at dysfunctional peripheral nerve endplates leads to central sensitization in the spinal cord. This in turn causes expansion of the affected dorsal horn neuron, creating referred regional pain that does not follow a dermatomal pattern, as seen in MPS. Another theory suggests that prolonged muscle contraction is an offending mechanism, resulting in local tissue ischemia and the accumulation of metabolic byproducts. These events perpetuate a cycle of motor and sympathetic activity that leads to a pain response, which can persist even after removal of the initial stimulus. Given these proposed pathophysiology’s of MPS, it is believed that mechanical disruption with a needle, with or without injectate, is necessary to terminate the nerve endplate dysfunction and allow for prolonged pain relief. Additionally rapid pain relief is seen after TPIs compared to non-invasive treatment, thus obligating the use of TPIs over other treatments.

Local Anesthetic with or without Steroid Compared with Normal Saline

The theory behind using local anesthetic in TPIs involves desensitization of free nerve endings, local vasodilation, and inhibition of the propagation of pain by its effect on sodium channels and thus endplate potentials. The theory behind adding a steroid to TPIs is that the anti-inflammatory effect can decrease peripheral sensitization and prevent progression to central sensitization.

The historically used injectate of lidocaine with or without the use of steroids has been extensively studied. Karadas et al. found that lidocaine was more effective than normal saline in TPIs for pain relief in patients suffering from chronic tension-type headaches. In this double-blind study, patients were randomized to receive TPIs with either normal saline or lidocaine 0.5% once every 3 days for three injections and then evaluated 3 months after treatment. While both groups experienced statistically significant decreases in number of painful days and visual analogue scale values, amount of analgesic used in a month, Hamilton Depression Rating Scale scores, and Hamilton Anxiety Rating Scale scores, the lidocaine group responded to treatment better than the normal saline group in all categories, with a statistical significance of p<0.001. This difference could potentially be explained by the increased frequency of the injections, and on the location of the TPIs, however, which in addition to specific...
muscle groups included injections at the exit points of the fifth cranial nerve and around the superior cervical ganglion. An unintentional nerve block at these locations could confound the finding that lidocaine offered superior outcomes compared to normal saline.

Following that study, Karadas et al. looked to see if repeated injections offered improved outcomes in patients with tension-type headaches in a double-blind study. Patients were randomized into four groups: 1. one injection of normal saline, 2. one injection of lidocaine 0.5%, 3. five injections of normal saline on alternate days, and 4. five injections of lidocaine 0.5% on alternate days. They found that the lidocaine groups statistically outperformed the normal saline groups at each time interval in the measured outcomes of frequency of painful days per month and visual analogue scale (p<0.05). Additionally, the group that received five injections of lidocaine was the only group that had persistent improvement at 6 months. Interestingly, this study also showed that the groups that received five injections compared to one had better outcomes regardless of the injectate, which may point to the utility of using a series of injections for MPS. Unlike the previous study, TPIs in this study were performed in targeted muscles and not near nerve exit points, thus decreasing the possibility of a direct nerve block confounding the results.

The utility of lidocaine in TPIs compared to normal saline is further illustrated in a study by Boelens et al., where researchers compared the effect of a single TPI using lidocaine 1% or saline to diagnose anterior cutaneous nerve entrapment syndrome in patients suffering from abdominal pain. Unsurprisingly, patients who received lidocaine demonstrated a successful response, defined as an improvement of at least 50% in the visual analogue scale score and/or an improvement of at least two points on a pain verbal rating scale; patients who received saline demonstrated a successful response, defined as an improvement of at least two points on the visual analogue scale score and/or an improvement of at least two points on a pain verbal rating scale; patients who received saline (p=0.007).

This study, along with others, again demonstrates that if nerve endings are blocked either intentionally or unintentionally there will be improved outcomes. However, in this study, patients received a larger injectate volume, 10cc, than is typically used in TPIs, and this high volume of injectate could have acted like a field block. In regard to follow-up, patients were only reassessed 15 to 20 minutes after the TPI, and thus the long-term utility for pain control cannot be determined. Furthermore, in this study patients only identified one trigger point, whereas patients with MPS typically have multiple trigger points, making the results of this study difficult to generalize.

There are also a number of studies showing that normal saline is a viable alternative to the traditional injectate of local anesthetic with or without steroid. Roldan et al. demonstrated in a single-blind, randomized study that TPIs with both normal saline and lidocaine 1% with triamcinolone 40 mg/mL in a 9:1 ratio as the CADM resulted in statistically significant reductions in the mean pain score on a numeric rating scale (p<0.001). In addition, size of effect and number needed to treat were similar between the two groups, demonstrating that normal saline is non-inferior to CADM in reducing pain. At the 2-week follow-up, the mean pain score, size of effect, and number needed to treat remained similar, suggesting that the type of injectate used was irrelevant.

Similar findings were seen in a double-blind study conducted by Sabatke et al., where patients were randomized to TPIs with normal saline, lidocaine 2%, or control (no injections). Both the normal saline and lidocaine groups had significantly reduced facial pain intensity, headache intensity, and weekly headache frequency compared to the control group (p<0.05); however, the injectate groups did not differ amongst themselves. While there continues to be evidence that TPIs are effective in treating myofascial pain, multiple researchers have shown that there is no difference in outcomes associated with type of injectate.

**Botulinum Toxin Compared with Normal Saline**

Botulinum toxins, most commonly BoNT-A, have come into favor as potential therapeutic injectates for TPIs. The toxins act by blocking the presynaptic release of acetylcholine from motor and autonomic nerve endings, leading to inhibition of skeletal muscle contraction and flaccid paralysis. This accounts for the toxins' antinociceptive and muscle-relaxant properties, which have been utilized clinically for the treatment of MPS and other musculoskeletal disorders.

Several studies have been performed to assess the role of botulinum toxins in TPIs. In a study by Benecke et al., the efficacy of TPIs with BoNT-A was investigated in patients with MPS of the cervical and/or shoulder muscles. Subjects were randomized into either the intervention group (BoNT-A injectate) or the control group (normal saline injectate). Results from this study did not show significant improvement with BoNT-A compared to saline at week 5, with 37/76 (49%) patients in the BoNT-A group showing response to treatment compared to 27/72 (38%) in the control group (p=0.1873). Statistically significant improvements in pain intensity compared to baseline were only seen in week 8 and were greater in the BoNT-A group than in the control group (p=0.008). Furthermore, duration of daily pain was reduced in the BoNT-A group from week 5, but statistically significant differences between the two groups were only seen at weeks 9 and 10 (p=0.04). Similar findings were seen in a double-blind study conducted by Sabatke et al, where patients were randomized to TPIs with normal saline, lidocaine 2%, or control (no injections). Both the normal saline and lidocaine groups had significantly reduced facial pain intensity, headache intensity, and weekly headache frequency compared to the control group (p<0.05); however, the injectate groups did not differ amongst themselves. While there continues to be evidence that TPIs are effective in treating myofascial pain, multiple researchers have shown that there is no difference in outcomes associated with type of injectate.
treatment, but there were no statistically significant differences between the two groups. The study concluded that BoNT-A was not superior to placebo in regard to the outcomes measured, claiming that a larger sample size of at least 140 patients was needed to achieve statistically significant results.

TPIs have also been utilized in the treatment of myofascial pelvic pain, as seen in Dessie et al., where the difference between BoNT-A and normal saline TPIs in pelvic floor muscles was evaluated. Results showed that after 2 weeks there was no significant difference between the two groups in self-reported pain upon palpation of most of the pelvic floor muscles. While subjects in the BoNT-A group reported greater declines in pelvic floor muscles palpation at the end of 12 weeks on the visual analogue scale, these differences were also not statistically significant (p=0.16 at both time points). Furthermore, the Pelvic Floor Distress Inventory score was significantly improved in the placebo group over the BoNT-A group at 2 weeks (p=0.013).

BoNT-A has also seen expanding application in the management of headaches. Harden et al. assessed the value of BoNT-A as a prophylactic treatment for chronic tension-type headaches with referred head pain in the cervical musculature. In this randomized, double-blind study, participants received either BoNT-A or normal saline placebo injections in cervical myofascial trigger points. There were greater reductions in headache frequency with BoNT-A compared to placebo (p=0.013); however, these effects declined by week 12. Decreased headache intensity was not significantly different between the two groups (p=0.80). There were no differences between the groups in any of the secondary outcome measures, which included cervical range of motion, trigger point threshold, and psychological assessment. Thus, the use of BoNT-A for tension-type headaches yielded mixed results, and further studies are needed to assess the toxin's true efficacy for this disorder.

Conclusion

Some postulate that the simple dilution of pain mediators such as substance P, cytokines, and calcitonin gene-related peptide with any injectate, irrespective of the type, mediates pain relief. Given this concept and multiple studies showing no difference in clinical outcomes between different injectates, we suggest the best way to select an injectate is based on side effect profiles and cost.

According to the mechanism of action of BoNT-A, it should be an effective treatment for MPS and has been used effectively for other pain syndromes. However, when reviewing the literature, we found that studies using BoNT-A for the treatment of myofascial pain have failed to prove superiority over normal saline when various outcome measures, including pain scores, pain duration, pain severity, and range of motion, are compared. This lack of evidence, as well as the high cost of a single BoNT-A injection, makes it a poor injectate choice.

Lidocaine with or without steroid has had mixed results in terms of efficacy for patients with MPS. What we can conclude from the studies is that local anesthetic is superior to normal saline only when nerve endings are either intentionally or unintentionally targeted. Beyond that, the efficacy of TPIs with local anesthetic compared to normal saline is equivocal, with some studies demonstrating that normal saline is non-inferior to CADM.

However, when comparing the potential side effects and cost of CADM to normal saline, normal saline has clear advantages over CADM. Steroid used in CADM can cause local skin thinning, muscle atrophy, and systemic effects such as dysregulation of hormone balance, decreased bone density, and uncontrolled blood glucose. Local anesthetic has a low side effect profile except in intravascular injection and in patients with allergies, thus the main downside is cost. Some studies do show that TPIs with local anesthetic can decrease post-injection soreness; however, there are no additional long-term benefits.

These are not insignificant considerations, especially in patients who, based on the natural history of myofascial pain, will most likely need repeated injections. Thus, based on efficacy, side effect profile, and cost, we believe that normal saline should be considered one of the first-line agents in TPIs.

Limitations and Future Directions

In reviewing the current literature on TPIs and myofascial pain, there are a number of limitations, including, but not limited to, small sample sizes and differences in local anesthetic type, volume, and concentration used; technique employed, such as location of TPIs and size of needle used; post-treatment management; duration and location of pain symptoms; and visual verification of TPI. Further studies elucidating these differences would strengthen the literature on the use of TPIs in the treatment of MPS.

Conflict of Interest

Authors report no conflicts of interest.

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References


